

SUMMARY OF REGISTRATION AND LISTING REQUIREMENTS FOR THE MANUFACTURE OR DISTRIBUTION OF HUMAN PHARMACEUTICALS		
TYPE OF FIRM	REGISTRATION STATUS	LISTING STATUS
Manufacturer [including homeopathic & controlled drugs]	yes	yes
Contract Manufacturer	yes	yes*
Own Label Distributor	no	yes
Wholesale Distributor	no	no
Own Label Repacker	yes	yes
Own Label Relabeler [including recirculizer]	yes	yes
Contract Relabeler	yes	no
Contract Testing Laboratory [dosage forms & active ingredient release]	yes	no
Contract Testing Lab [doing non-release tests]	no	no
Contract Sub-Manufacturer	yes	no
IND Manufacturer [Clinical Drugs]	no	no
NDA and ANDA Manufacturer	yes	yes
Sponsor/Monitors/Clinical Investigator	no	no
Contract Sterilizer	yes	no
Fulfillment Packager [adding substantive labeling]	yes	no
Mail Order House [adding insubstantial labeling]	no	no
Printing House	no	no
Medical Gas Transfiller	yes	yes
First Aid/Rescue Squad [transfilling for own use]	no	no
Medical Gas Transfiller [operating out of a van]	yes	yes
Contract Assembler	yes	no
Active Drug Substance Manufacturer	yes	yes
Excipient Drug Manufacturer	no	no
Manufacturer of Research Drugs	no	no
Drug Importer	no	no
Foreign Drug Manufacturer	yes	yes
Methadone Clinic	no	no
Retail Pharmacy	no	no
Manufacturing Pharmacy	yes	yes
Regional Admixture Pharmacy	yes	no

*Products packaged/marketed under the contract manufacturer's own label must be listed by the Contract Manufacturer.